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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	
09/304,564	05/04/99	CHOKRI		M	USD-93-AG-ID
C 000466 YOUNG & THOMPSON 745 SOUTH 23RD STREET		HM12/1004 2ND FLOOR	-ŋ   		EXAMINER
				HOLLERAN, A	
				ART UNIT	PAPER NUMBER
ARLINGTON V				1642	6
				DATE MAILED	" 10/04/00 `

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

# Office Action Summary

Application No. 09/304,564 Applicant(s)

Examiner

**Group Art Unit** 

Chokri et al

Anne Holleran 1642 Responsive to communication(s) filed on \_\_\_\_\_\_ This action is FINAL. ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/1935 C.D. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire \_\_\_\_\_\_3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Disposition of Claim is/are pending in the applicat X Claim(s) 1 and 2 Of the above, claim(s) \_\_\_\_\_\_ is/are withdrawn from consideration Claim(s) is/are allowed. X Claim(s) 1 and 2 is/are rejected. ☐ Claim(s) \_\_\_\_\_\_ is/are objected to. ☐ Claims \_\_\_\_\_\_ are subject to restriction or election requirement. **Application Papers** ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. ☐ The drawing(s) filed on \_\_\_\_\_\_ is/are objected to by the Examiner. ☐ The proposed drawing correction, filed on \_\_\_\_ is approved disapproved. The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). None of the CERTIFIED copies of the priority documents have been ☐ All ☐Some\* received. received in Application No. (Series Code/Serial Number) \_\_\_\_ received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \*Certified copies not received: ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of References Cited, PTO-892 [X] Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_3, 4\_\_\_ ☐ Interview Summary, PTO-413 □ Notice of Draftsperson's Patent Drawing Review, PTO-948 □ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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### **DETAILED ACTION**

1. Claims 1 and 2 are pending.

Claims 1 and 2 are examined on the merits.

## Claim Rejections - 35 USC § 112

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of the phrase "predetermined macrophages". It is not clear from the specification what is encompassed by predetermined macrophages and it is not clear how this phrase adds a limitation to the specificity of the claimed bispecific antibodies. For the purposes of examination, claim 1 will be interpreted to be drawn to bispecific antibodies which recognize both macrophages and tumor cells:

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Chokri et al (Chokri, M. et al., Res. Immunol, 143: 95-99, 1992).

Claim 1 is drawn to bispecific antibodies which recognize both an antigen of macrophages and an antigen of a tumor cell. Claim 1 further recites properties of a sub-species of macrophage. However, absent evidence to the contrary, it is assumed that the macrophages described in claim 1 express antigens that are found on any macrophage.

Chokri et al teach a bispecific antibody which recognizes both the FcyRI of macrophages and recognizes human adenocarcinoma antigen (see abstract). Thus, Chokri et al teach bispecific antibodies which are the same as that claimed.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,959,084 (Ring et al., published Sep. 28, 1999; effective filing date Oct. 29, 1990).

The subject matter of claim 1 is discussed above. Claim 2 is drawn to a method of treating cancer comprising administering the bispecific antibodies of claim 1.

U.S. Patent 5,959,084 discloses methods of treating cancer and claims bispecific antibodies which are the same as that of claims 1 and 2 (see column 24, line 60 -column 25, line 35 and column 26, claims 1-9). The bispecific antibodies of U.S. Patent 5,959,084 bind to Fc receptors of cytotoxic cells and to tumor cells over-expressing P-glycoprotein. The Fc receptor may be a FcγRIII receptor which is expressed by macrophages (column 2, lines 62-63).

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5. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,635,600 (Fanger et al., published June 3, 1997; effective filing date Feb. 2, 1988).

U.S. Patent 5,635,600 discloses and claims bispecific antibodies which bind to Fc receptors for IgG and which also bind to cancer cells (see claims 11 and 12 and column 17, line 54 - column 18, line 30). Thus, U.S. Patent 5,635,600 discloses and claims bispecific antibodies and methods of treating cancer which are the same as that claimed.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/05871 (Medarex, Inc., published 2 May 1991).

WO 91/05871 teaches bispecific antibodies which are specific for Fc gamma receptors and tumor cells (see abstract and page 2, line 4 - page 5, line 21) and methods of treating cancer (see claim 26). Thus, WO 91/05871 teaches bispecific antibodies and methods of treating cancer that are the same as that claimed.

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran Patent Examiner October 1, 2000

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600